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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/362,598	07/28/1999	JOEL V. WEINSTOCK	3948/79934	7062

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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/362,598	WEINSTOCK ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,26 and 28-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,26 and 28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-18-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 11-25-2005 are acknowledged. Claim 32 has been amended. Claims 24, 26 and 28-32 are pending and currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 11-18-2005 has been considered. An initialed copy is attached hereto.

Claim Rejection Withdrawn

The rejection of claim 32 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase ""as evidenced by an *in vitro* assay" is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The instant claims are drawn to a method of screening a helminthic preparation for one or more components that reduce a Th1 immune response. The method comprises preparing and fractionating and sub-fractionating the preparation and assaying the products for the ability to reduce a Th1 immune response.

The rejection of claims 24, 26 and 28-32 under 35 U.S.C. 103(a) as being unpatentable over Kullberg et al. (Journal of Immunology, 1992, Vol. 148, No. 10, pages 3264-3270 -- IDS) is maintained for reasons of record.

Applicant argues:

1. One of skill in the art would not have been motivated to make fractions and subfractions of the *S. mansoni* preparations to produce a pure composition capable of reducing Th1 response.
2. Kullberg et al. focus only on the implications of *S. mansoni* infection on the response of the infected mammal to non-parasite antigen.
3. There is not teaching or suggestion in Kullberg et al. that *S. mansoni* could or should be used to decrease Th1 immune responses or be used as a therapeutic agent.
4. There is no teaching in Kullberg relating to the use of *S. mansoni* with the goal of reducing a Th1 response.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 2, the instant claims do not limit the antigen to which the measured immune response is directed. The instant claims are drawn to "a method of screening a helminthic parasite preparation for one or more components that reduce **a Th1 immune response**..." This encompasses immune responses to any antigen.

With regard to Points 2 and 3, the instant claims are drawn to a method of screening a helminthic parasite preparation for one or more components that reduce **a** Th1 immune response, not a method of using said components. Hence, Applicant's arguments are not germane.

With regard to Point 1,Kullberg et al. disclose the helminthic parasite *Schistosoma mansoni* down regulates the Th1 cytokine secretion of IL-2 and IFN-γ in mice (see abstract). Kullberg et al. further disclose that Th1 responses were determined by cytokine profiles as measured by *in vitro* ELISA assays (see materials and methods and results sections). Kullberg et al. differs from the instant invention in that they don't disclose the method steps of fractionating, sub-fractionating and testing of the sub-fractionates. However, as attested to by Drs. Weinstock and Elliot in their Declaration filed under 37 C.F.R 1.132 on 12-9-2005: "fractionation and testing of resulting fractions and sub-fractions for activity, as claimed, is a well-known and routine method for isolating the biologically active component(s) of a complex biological mixture. It is also well known in the art that the same assay can be used at each stage of a fractionation procedure to monitor which fraction(s) or sub-fraction(s) have the activity of interest" (see point 4 of Declaration). Consequently, it would have been obvious for one of ordinary skill in the art to use these "well known and routine methods" to identify the component(s) of the parasite composition responsible for the down regulation of Th1 cytokine

secretion. One would have been motivated to identify said component(s) in order to produce a "pure" composition capable of reducing a Th1 response without the possible negative effects of caused by the other constituents of the nematode composition. One would have had a reasonable expectation of success since said methods are well known and routine in the art.

The rejection of claims 24, 26 and 28-32 under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (WO 96/29802 – IDS) is maintained for reasons of record.

Applicant argues:

1. One of skill in the art, given the teachings of Lee et al. would not have been motivated to perform the steps of fractionation, subfractionation and testing of the subfractions to identify an active component because there is not teaching or suggestion in Lee et al. to identify an active component.

2. A showing of motivation must be clear and particular.

3. The Office relies on the assertion that the technical no how to fractionate a sample was known in the art, however the mere fact that a device or process is known does not alone make that device or process obvious.

Applicant's arguments have been fully considered and deemed non-persuasive.

As outlined previously, the skilled artisan would have been motivated to identify "active component" in order to obtain a "pure" composition in order to reduce the possible deleterious effects (i.e. non-specific immune responses etc). Since said compositions are administered to

allograft (transplant) patients, the skilled artisan would necessarily want to minimize unwanted immune activators.

As outlined previously, Lee et al. disclose the down regulation of Th1 activity in mice can be accomplished by the administration of soluble helminthic nematode extract (see page 5, line 21 to page 6, line 4 and page 10)). Lee et al. further disclose that Th1 responses were determined by cytokine profiles as measured by *in vitro* ELISA assays (see Example 2). Lee et al. differs from the instant invention in that it does not explicitly disclose the method steps of fractionating, sub-fractionating and testing of the sub-fractionates. However, as attested to by Drs. Weinstock and Elliot in their Declaration filed under 37 C.F.R 1.132 on 12-9-2005: "fractionation and testing of resulting fractions and sub-fractions for activity, as claimed, is a well-known and routine method for isolating the biologically active component(s) of a complex biological mixture. It is also well known in the art that the same assay can be used at each stage of a fractionation procedure to monitor which fraction(s) or sub-fraction(s) have the activity of interest" (see point 4 of Declaration). Consequently, it would have been obvious for one of ordinary skill in the art to use these "well known and routine methods" to identify the component(s) of the parasite composition responsible for the down regulation of Th1 cytokine secretion. One would have been motivated to identify said component(s) in order to produce a "pure" composition capable of reducing a Th1 response without the possible negative effects of caused by the other constituents of the nematode composition. One would have had a reasonable expectation of success since said methods are well known and routine in the art.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ROBERT A. ZEMAN
PATENT EXAMINER
December 11, 2006